K021227 1/4 JUN 2 6 2002

Summary of Safety and Effectiveness Information	ZAP LASERS, LLC
Premarket Notification, Section 510(k)	APRIL 15, 2002

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1. Device Name:

Trade Name: ***SoftLase G2 - Surgical Diode Laser System***
Common Name(s): Surgical Laser System
Classification Name(s): Laser, Surgical

2. Establishment Name & Registration Number:

Name: ZAP LASER, LLC
Number: applied/pending

3. Classification(s):

§ 878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology. (a) Identification. (1) A carbon dioxide laser for use in general surgery and in dermatology is a laser device intended to cut, destroy, or remove tissue by light energy emitted by carbon dioxide. (2) An argon laser for use in dermatology is a laser device intended to destroy or coagulate tissue by light energy emitted by argon.

(b) Classification. Class II.

Device Class: Class II for all requested indications
Classification Panel: General and Plastic Surgery & Others
Product Code(s): GEX

4. Section 514 Compliance

ZAP LASERS, LLC intends to comply fully with the general controls authorized under Sections 501, 502, 510, 516, 518, 519, and 520 of the Food, Drug, and Cosmetic Act.

5. Performance Standards

United States Food and Drug Administration mandated performance standards for this device exist and are provided under Sections 21 CFR 1010 & 1020. In addition, various voluntary performance standards are utilized. Voluntary standards utilized include Standard Operating Procedures, vendor & process certification and qualification procedures, Quality Systems Regulations, ISO materials standards and cGMP & ISO 9000 series quality regulations.

ZAP LASERS, LLC also meets appropriate general controls authorized under Sections 501, 502, 510, 516, 518, 519, and 520 of the Food, Drug, and Cosmetic Act.

6. Special Controls:

All Class II devices are subject to Special Controls.

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7. ***Labeling:***

The laser system discussed in this premarket notification will be manufactured by Zap Lasers, LLC and labeled as such. Zap Lasers, LLC will market the system exclusively to healthcare facilities, physicians and dentists. In addition to the usual package and identification labeling, the following additional Warnings, Cautions & Precautions statements are displayed as appropriate on or within the device packaging. They are repeated here for ease of review.

Warning: Federal (United States) Law restricts this device to sale by or on the order of a physician or dentist only.

8. ***Summary Basis of Equivalence:***

There are no unique applications, indications, material or specifications presented herein. Evidence of equivalence has been demonstrated through:

- The SoftLase G2 intended use and indications for use were previously cleared by FDA for the predicate devices.
- The technical characteristics of the SoftLase G2 are similar to those of the cleared SoftLase, Aurora HL and Twilite lasers.
- Laser output values of the SoftLase G2 are well within previously cleared values of the predicate dental laser systems as described.
- The predicate devices and other previously cleared laser systems with similar power outputs have a proven safety and effectiveness in the treatment of the claimed indications.
- Safety and performance testing.

Therefore, the SoftLase G2 Surgical Diode Laser System is substantially equivalent to its predicate devices cited above and raises now new safety and/or effectiveness issues.

9. ***Predicate Device*** *(legally marketed comparison device)*

Zap Lasers, Inc. believes that the following surgical laser systems are substantially equivalent to the SoftLase - Surgical Laser Diode System:

1. SOFTLASE (K003440, ZAP Lasers, Inc.); 2. AURORA HL (K992374, Premier Laser Systems, Inc.) and 3. TWILITE (K003385, Biolase Technology, Inc.).

To assist in the overall evaluation of the referenced surgical laser systems, the following Feature Comparison Table presents a brief graphic illustration of the primary features.

FEATURE	*SoftLase G2 - Surgical Diode Laser System*	SoftLase, Aurora HL & Twilite	SE?
Type of laser	Diode laser	Diode laser	YES
Wavelength	808 ± 5 nm	808 ± 5 nm (SoftLase); 810 nm (+ 170 nm, -30 nm) (Aurora HL); 815 ± 15nm (Twilite)	YES
Max output power	3.5 Watt	3.5 Watt (SoftLase); 1.5 Watt (Aurora HL); 7 Watt (Twilite)	YES
Operation mode	Continuous wave and pulsed	Continuous wave and pulsed	YES
Delivery system	Multi-mode 400/600 um core quartz fiber	Multi-mode 400/600 um core quartz fiber	YES

Fiber aiming beam	5 mw diode laser, 650 nm	5 mw diode laser, 650nm	YES
Activation means	Foot-switch	Foot-switch	YES
Intended Use and Indications for Use	-Excision and Incision Biopsies -Hemostatic assistance -Treatment of Apthous Ulcers -Frenectomy -Frenotomy -Gingival Incision and Excision -Gingivectomy -Gingivoplasty -Incising and Draining of Abscesses -Operculectomy -Oral Papillectomy -Removal of Fibromas -Exposure of unerupted teeth -Soft Tissue Crown Lengthening -Sulcular Debridement (removal of diseased or inflamed soft tissue in the periodontal pocket) -Tissue retraction for Impression -Vestibuloplasty	Same	YES
	-Light activation of bleaching materials for teeth whitening -Laser-assisted bleaching / whitening of teeth	Same	YES

*10. **Device Description:***

The laser diode assembly with fiber bundle, which contains 3 single diode lasers, each of 1.6 watt output power (Class IV lasers) lasing at about 808 nm. Each diode laser is coupled directly into a 200 um core optical fiber using a special positioner. The assembly also contains a 5-mw power - 650 nm pilot laser diode, which is coupled into the three core fibers. In the second version of the device, a single 5 Watt laser diode is used. A special optical system is implemented to focus its laser diode radiation into a delivery fiber. It allows an effective use of 300 um and 200 um fibers. In both versions, a visible light of pilot laser is used for aiming the tip of the delivering fiber onto the tissue.

The laser diode power supply, with two controller PCBs supplies power to the diodes in DC or pulsed mode.

The delivery fiber cables, consist of multi-mode, single core optical fibers available in 200, 300, 400 and 600 um diameters. The standard SMA 905 fiber connector terminates one end of the delivery fiber, which is attached to the SMA union at the rear panel of the laser box. The other end of the fiber is stripped of its protective jacket and is cleaved to provide laser radiation output.

The foot-switch, is a standard (UL-approved) commercial foot-switch/pedal that provides hands-free ON/OFF capabilities. This controls initiation/termination of laser power from the distal end of the delivery fiber. Each ***SoftLase G2*** laser system is provided with two safety goggles, one fiber stripper and one sapphire wedge scribe for fiber cleaving.

11. Applicant Name & Address:

Zap Lasers, LLC
2643 Pleasant Hill Road
Pleasant Hill, CA 94523

12. Company Contact:

Jay Goble, DDS
Zap Lasers, LLC
2643 Pleasant Hill Road
Pleasant Hill, CA 94523
Phone: 888-876-4546
Fax: 925- 692-2063

13. Submission Correspondent:

Jay Goble, DDS
Zap Lasers, LLC
2643 Pleasant Hill Road
Pleasant Hill, CA 94523
Phone: 888-876-4546
Fax: 925-692-2063

14. Manufacturing Facility:

The devices are physically manufactured at ZAP Laser, LLC premises in Pleasant Hill, CA. The devices are manufactured by Zap Lasers, LLC for distribution in the U.S.A.

15. Sterilization, Packaging & Storage Information:

The diode laser device is not supplied sterile. The hand-piece, which secures the working end of the fiber, is sterilizable as well as fiber itself. The plastic canula, which is attached to the end of the hand-piece and fixes the position of fiber tip is disposable. A special disinfecting protocol is developed for fiber stripping/cleaving.

Packaging materials are typical medical grade tubes, plastic trays, peel-type pouches of the generic mylar/non-woven sandwich variety, etc. All packages should be intact upon receipt. Packaging should be inspected on arrival for evidence of shipping damage. Damaged packaging may indicate the presence of unsafe product and it should not be used until carefully inspected. If the package or product is damaged, the product should not be used and should be returned. Product must be handled, stored and opened in such a way that it is protected from inadvertent damage or contamination. When used, the product must be placed into use following cleaning, sterilization and accepted surgical sterile technique.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 6 2002

Zap Lasers, LLC
Jay Goble, DDS
President
2643 Pleasant Hill Road
Pleasant Hill, California 94523

Re: K021227
Trade Name: Softlase G2-Surgical Diode Laser System
Regulation Number: 878.4810
Regulation Name: Laser Surgical Instrument
Regulatory Class: II
Product Code: GEX
Dated: April 15, 2002
Received: April 18, 2002

Dear Dr. Goble:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

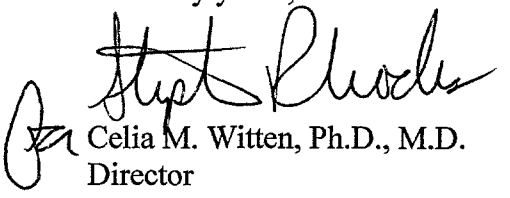
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K021227

Device Name(s): ***SoftLase G2 - Surgical Diode Laser System***

Intended Use(s) of the Device:

The ***SoftLase G2 - Surgical Diode Laser System*** is to provide the ability to perform intraoral soft tissue dental, general, oral maxillo-facial and cosmetic surgery. The ***SoftLase G2*** is intended for ablating, incising, excising, vaporization and coagulation intraoral soft tissues using a contact fiber optic delivery system. The system is also intended for use in teeth whitening procedures.

The device will be used in the following areas: general and cosmetic dentistry otolaryngology, arthroscopy, gastroenterology, general surgery, dermatology & plastic surgery, neurosurgery, gynecology, urology, ophthalmology and pulmonary surgery. The following are the indications for use for which the device will be marketed:

-Excision and Incision Biopsies
-Hemostatic assistance
-Treatment of Apthous Ulcers
-Frenectomy
-Frenotomy
-Gingival Incision and Excision
-Gingivectomy
-Gingivoplasty
-Incising and Draining of Abscesses
-Operculectomy
-Oral Papillectomy
-Removal of Fibromas
-Exposure of interrupted teeth
-Soft Tissue Crown Lengthening
-Sulcular Debridement (removal of diseased or inflamed soft tissue in the periodontal pocket)
-Tissue retraction for Impression
-Vestibuloplasty
-Light activation of bleaching materials for teeth whitening
-Laser-assisted bleaching / whitening of teeth

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

Prescription Use X (Per 21 CFR 801.109)

Over-The-Counter Use _____ (Optional format 1-2-96)

510(k) Number K021227